



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,837	06/25/2001	Anand V. Gumaste	MICRODOSE 00.01	9414

7590 08/13/2002

Norman P. Soloway  
HAYES, SOLOWAY, HENNESSEY, GROSSMAN & HAGE, P.C.  
130 W. Cushing Street  
Tucson, AZ 85701

EXAMINER

PATEL, NIHIR B

ART UNIT	PAPER NUMBER
----------	--------------

3743

DATE MAILED: 08/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/888,837

Applicant(s)

GUMASTE, ANAND V.

Examiner

Nihir Patel

Art Unit

3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 4-7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 8-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

This application contains claims directed to the following patentably distinct species of the claimed invention:

- Figure 2 (claim 3)
- Figure 3 (claims 4 and 6)
- Figure 4 (claims 3 and 6)
- Figure 5 (claims 3 and 7)

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 5 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Norman P. Soloway on August 1, 2002 a provisional election was made with traverse to prosecute the invention of species 2 (figure 2), claim 3. Affirmation of this election must be made by applicant in replying to this Office action. Claims 4, 6, and 7 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

### **DETAILED ACTION**

#### ***Election/Restrictions***

1. Claim 5 is hereby withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to non-elected species or inventions, there currently being no allowable generic claim or linking claim. Election was made with traverse.

#### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Eisele et al. U.S.

Patent No. 6,029,663. Referring to claim 1, Eisele discloses a dry powder inhaler delivery system that comprises an elongated bottom element (48), having a frangible overlying top element defining a plurality of spaced top crowned areas (54) containing powder or liquid material (62). Refer to figure 5 and column 3 lines 10 through 20.

Referring to claim 2, Eisele shows that the lower element (48) comprises an elongated flexible tape. Refer to figure 5 and column 3 lines 20 through 30.

Referring to claim 8, Eisele shows that the material comprises a medication. Refer to figure 5 and column 3 lines 10 through 20.

Referring to claim 13, Eisele shows that the size and number of holes together with volume formed by the blister pack are optimized for de-aggregation and aerosolization of material in the blister pack. Refer to figures 8 and 9.

Referring to claim 14, Eisele shows that the height and shape of the blister pack is optimized for de-aggregation and aerosolization of material in the blister pack. Refer to figures 8 and 9.

Referring to claim 15, Eisele shows that the interface to the vibrator is optimized for optimum coupling of the energy into the blister pack for de-aggregation and aerosolization of material in the blister pack. Refer to figure 1C.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eisele et al. U.S. Patent No. 6,029,663 in view of Eisele et al. U.S. Patent No. 5,921,237.

Eisele discloses the applicant's invention as claimed with the exception of providing a top crowned areas that are shaped as inverted cones.

Eisele discloses a dry powder inhaler that does provide a top crowned areas that are shaped as inverted cones. Therefore it would be obvious to modify Eisele's invention by

providing a top crowned areas that are shaped as inverted cones in order save space in the blister pack.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eisele et al. U.S. Patent No. 6,029,663 in view of Pera U.S. Patent No. 5,944,012.

Eisele discloses the applicant's invention as claimed with the exception of stating that the material comprises a vitamin.

Pera discloses a method for dispensing antioxidant vitamin by inhalation background of the invention that does state that the material comprises a vitamin. Therefore it would be obvious to modify Eisele's invention by stating that the material comprises a vitamin so that one knows the limitations of the invention.

Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eisele et al. U.S. Patent No. 6,029,663 in view of Hendricks U.S. Patent No. 5,699,789.

Eisele discloses the applicant's invention as claimed with the exception of stating that the material comprises a hormone or a steroid.

Hendricks discloses a dry powder inhaler that does state that the material comprises a hormone or a steroid. Therefore it would be obvious to modify Eisele's invention by stating that the material comprises a hormone or a steroid so that one knows the limitations of the invention.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eisele et al. U.S. Patent No. 6,029,663 in view of Shyjan U.S. Patent No. 6,312,909.

Eisele discloses the applicant's invention as claimed with the exception of stating that the material comprises a bioactive material.

Art Unit: 3743

Shyjan discloses a compositions and methods for the diagnosis prevention and treatment of tumor progression that does state that the material comprises a bioactive material. Therefore it would be obvious to modify Eisele's invention by stating that the material comprises a bioactive material so that one knows the limitations of the invention.

***Conclusion***

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Nihir Patel whose telephone number is (703) 306-3463. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:30 pm. If attempts to reach the examiner by telephone are unsuccessful the examiner supervisor Henry Bennett can be reached at (703) 308-0101.

NP  
August 7, 2002

  
SPE 3743  
8/9/02